Remarks

The Office Action mailed June 3, 2010 has been received and reviewed. Claims 1-8 are pending, of which claim 8 has been withdrawn from consideration, leaving claims 1-7 as pending and under examination. Applicant respectfully requests reconsideration and withdrawal of the rejections.

The 35 U.S.C. §103 Rejection

Claims 1-7 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,488,040 (Jamas). Applicant respectfully traverses.

Applicant respectfully submits that Jamas fails to render Applicant's claims unpatentable because, at a minimum, Jamas fails to set forth each and every feature recited in Applicant's claims.

Claims 1, 4, and 5 are independent. Each of the remaining claims depends, directly or indirectly, from one of the independent claims and therefore includes all of the features of the independent claim from which it ultimately depends. Thus, remarks that refer, either specifically or generally, either individually or collectively, to one or more of claims 1, 4, and 5 apply equally to any claim that depends from an identified independent claim.

Each of claims 1, 4, and 5 is drawn to a method that involves enhancing activities of committed stem cells by administering to an individual whole glucan particles (WGP). Claim 1 is drawn to a method of enhancing glucan-mediated committed stem cell proliferation and expansion. Claim 4 is drawn to a method of enhancing tissue repair via committed stem cell recruitment. Claim 5 method of enhancing glucan-mediated committed progenitor stem cell recovery.

In contrast, Jamas discloses using neutral soluble glucan – not whole glucan particles – to enhance hematopoietic stem cell activities to stimulate platelet formation. (Jamas, column 1, line 62 through column 2, line 12, and column 3, lines 27-28). Thus, compared to Applicant's claims 1, 4, and 5, Jamas discloses using a different form of β-glucan in order to enhance the activity of a different population of stem cells. Applicant respectfully asserts that Jamas fails to establish a *prima facie* case of obviousness against claims 1, 4, and 5.

The Office Action asserts, "the instant specification (see page 3) states that committed stem cells can include progenitor cells." (Office Action, page 3). Applicant respectfully submits that Applicant's specification clearly distinguishes the committed stem cells involved in the claimed methods from the hematopoietic stem cells and/or hematopoietic progenitor cells disclosed in Jamas. Applicant's specification teaches, "The committed stem cells can be progenitor cells for various organs or tissues such as cardiac stem cells, hepatic stem cells, kidney stem cells, neuronal stem cells, muscle stem cells as well as other stem cells." (Specification, page 3, lines 12-15). None of the exemplary stem cell populations necessarily includes hematopoietic stem cells. In addition, Applicant's specification teaches, "The CR3/glucan receptor is present on a wide variety of committed stem cell progenitors as well as hematopoietic stem cells." (Specification, page 8, lines 5-8, emphasis added). In choosing this language, Applicant characterizes hematopoietic stem cells (as disclosed in Jamas) as a distinct cell population from committed stem cells (as recited in claims 1, 4, and 5) rather than as a subset population of committed stem cells, as suggested in the Office Action.

The Office Action acknowledges that while "Jamas does not teach the administration of whole glucan particles (WGP) in its method, the soluble β-glucans are made from WGP and according to the teachings in the background of the reference, both the soluble and WGP will increase (proliferate) the number of stem cells." (Office Action, page 3). As stated above, Jamas teaches only that both soluble and WGP can increase numbers of hematopoietic stem cells and provides no information regarding the ability of any form of β-glucan to increase numbers of non-hematopoietic committed stem cells.

In addition, Jamas teaches the preparation of neutral soluble glucan from insoluble glucan particles. (Jamas, column 5, lines 27-29). That is, insoluble glucan particles are a starting material from which the neutral soluble glucan is extracted. (Jamas, column 5, lines 50-54, and column 5, line 55 through column 7, line 38). There is no basis, as the Office Action suggests, that the neutral soluble glucan disclosed in Jamas and WGP are interchangeable. Indeed, Jamas expressly teaches that neutral soluble glucan "selectively activate[s] only those components that are responsible for the initial response to infection, without stimulating or priming the immune

system to release certain biochemical mediators (e.g., IL-1, TNF, IL-6, IL-8 and GM-CSF)[.]" (Jamas, column 7, lines 59-64). Jamas also teaches that neutral soluble glucan "retains a specific subset of immunological properties common to β-glucans but uniquely does not induce the production of IL-1 and TNF[.]" (Jamas, column 3, lines 44-48). Moreover, the immunological properties common to β-glucans referred to in this passage of Jamas once again refers to hematopoietic activity of β-glucans and therefore provides no predictive information whether any form of β-glucan has any effect on the proliferative activity of non-hematopoietic committed stem cells.

Jamas therefore expressly teaches that the neutral soluble glucan described therein possesses different biological activities than prior forms of β-glucan. This teaching is reiterated in Applicant's specification, where neutral soluble glucan is described at, for example, page 6, lines 23-29, while WGPs are described as "another form of β-glucan" and described in detail at, for example, from page 6, line 30 through page 7, line 20.

Thus, Jamas teaches using a different and non-interchangeable form of β-glucan than recited in Applicant's claimed methods to induce proliferation of a different – i.e., hematopoietic stem cells as opposed to committed stem cells, as characterized in Applicant's specification (page 8, lines 5-6) – population of stem cells than are recited in Applicant's claimed methods.

The Office Action acknowledges, "Jamas does not teach wherein the committed stem cells are selected from the group consisting of stem cells from the liver, heart, muscle, kidney and neural tissue." (Office Action, page 3). The Office Action asserts, however, that Patchen *et al.* (U.S. Patent No. 6,117,850) teaches a method of inducing mobilization of peripheral blood precursor and progenitor cells from hematopoietic organs – once again, hematopoietic stem cells (Patchen *et al.*, column 3, lines 34-37) – by administering aqueous soluble β-glucan. Applicant respectfully submits that the disclosure of Patchen *et al.* does not cure the deficiencies in the Office Action's asserted *prima facie* case of obviousness.

First, it is unclear whether Patchen *et al.* is intended to be part of the rejection. M.P.E.P. §706.02(b) states, "Where a reference is relied on to support a rejection, whether or not in a minor capacity, that reference should be positively included in the statement of the rejection."

The statement of rejection states, simply, "Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamas et al [sic] (US 5,488,040)." (Office Action, page 2).

Second, the disclosure of Patchen *et al.*, like the disclosure Jamas, is limited to the use of soluble β-glucan to induce proliferation of hematopoietic stem cells and provides no information regarding inducing proliferation of committed stem cells, which are characterized in Applicant's specification as distinct from hematopoietic stem cells.

Thus, Applicant respectfully submits that claims 1-7 are patentable over Jamas, alone or in combination with Patchen *et al.* Compared to Applicant's claims 1, 4, and 5, Jamas discloses using a different form of β-glucan in order to enhance the activity of a different population of stem cells. The Office Action acknowledges that Jamas fails to teach the features recited in Applicant's claimed methods: administering WGP and inducing proliferation of non-hematopoietic committed stem cells. Yet, the Office Action fails to provide any technical authority, especially in the face of the express disclosures of Jamas and Applicant's specification, supporting the alleged obviousness of the modifications of Jamas that are required in order to practice Applicant's claimed methods.

Patchen *et al.* fails to provide any disclosure that cures the deficiencies of Jamas.

Because Jamas – and, for that matter, the combination of Jamas and Patchen *et al.* – fails to set forth all of the features recited in claims 1, 4, and 5, Applicant respectfully submits that claims 1-7 are nonobvious over either Jamas alone or the combination of Jamas and Patchen *et al.* Applicant therefore requests that the rejection of claims 1-7 under 35 U.S.C. §103(a) as being unpatentable over Jamas be reconsidered and withdrawn.

Request for Rejoinder

Applicant respectfully requests rejoinder of claim 8 under M.P.E.P. §821.04(a) as requiring all the limitations of an allowable claim. Claim 8, like independent claims 1-7 is drawn to a method that involves administering to an individual whole glucan particles to enhance committed stem cell proliferation.

Summary

Applicant respectfully submits that claims 1-8 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representative at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

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The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop **Amendment**, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of November, 2010.

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